## 6. 510(k) Summary

APR - 1 2011

### Submitter Information

A. Company Name: Baylis Medical Company Inc.

B. Company Address: 2645 Matheson Blvd. East
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Canada

C. Company Phone: (905) 602-4875; ext 252

D. Company Facsimile: (905) 602-5671

E. Contact Person: Meghal Khakhar

F. Summary Prepared on: October 04, 2010

### Device Identification

A. Device Trade Name: TorFlex™ Transseptal Guiding Sheath

B. Device Common Name: Dilator; Sheath; J-tipped Guidewire

C. Classification Name: 1) Catheter introducer
2) Vessel dilator for percutaneous catheterization
3) Percutaneous catheter

D. Device Class: Class II

E. Device Code: 1) DYB
2) DRE
3) DQY

### Identification of Predicate Device

The predicate device is the TorFlex™ Transseptal Guiding Sheath, which is cleared under 510(k) Premarket Notification Number K013919. Modifications to the current device include changes to the sheath design and materials, kit packaging, and device manufacturer and sterilizer. The indication for use, operation principle, and fundamental scientific technology of the original and proposed TorFlex™ Transseptal Guiding Sheath remains the same.

### Device Description

The TorFlex™ Transseptal Guiding Sheath kit consists of three components: a sheath, a dilator, and a J-tipped guidewire.

The TorFlex™ Transseptal Guiding Sheath is designed for safe and easy catheterization and angiography of specific heart chambers and locations. The sheath provides superior torque control and is flexible. The radiopaque tip maximizes visualization of the sheath during manipulation. The dilator provides support for the sheath and has a tapered tip.

**Intended Use**

The TorFlex™ Transseptal Guiding Sheath is used for the percutaneous introduction of various types of cardiovascular catheters to all heart chambers, including the left atrium via transseptal perforation / puncture.

**Substantial Equivalence**

The proposed and 510(k)-cleared TorFlex™ Transseptal Guiding Sheath (K013919) are determined to be substantially equivalent with respect to fundamental scientific technology.

This determination is based upon results from performance tests as listed below:

**i) Biocompatibility Testing**

Test information and results for the following biocompatibility tests demonstrate that the device is safe for its intended use:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Systemic Toxicity (Acute)
- Hemocompatibility
- Pyrogenecity

**ii) Mechanical Testing**

The following tests were performed and determined that the device is able to withstand the following physical stresses without failure:

- Torque transmission + Strength of union –Torque test
- Flow rate measurement
- Three point bend test
- Freedom from liquid leaking through hemostasis valves + valve integrity
- Freedom from air leakage through hemostasis valves + valve integrity
- Freedom from liquid leakage
- Freedom from air leakage
- Strength of union-Pull test
- Valve insertion force
- Tip transition
- Snap fit

### iii) General Physical Testing

The following general physical characteristics of the device were evaluated:

- Surface Defects
- Corrosion Resistance

### iv) Bench Testing

Bench testing was performed to assess the compatibility of the sheath with 8F devices.

### v) Sterlization Validation

Sterilization Validation for the TorFlex™ Transseptal Guiding Sheath was conducted as per ANSI/AAMI/ISO 11135-1 and FDA Guideline on Validation of the Limulus Amebocyte Lysate (LAL) Test as an End-Product Endotoxin Test. Ethylene Oxide residue levels are in compliance with ISO 10993-7.

### vii) Packaging Validation

The packaging for the TorFlex™ Transseptal Guiding Sheath Kit has been validated in accordance with ANSI/AAMI/ISO 11607.

The test results demonstrate that the proposed device is safe and effective and performs as per the intended use. The proposed and 510(k)-cleared TorFlex™ Transseptal Guiding Sheath (K013919) are determined to be substantially equivalent with respect to fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Baylis Medical Co., Inc.
c/o Mr. Meghal Khakhar
Manager, Regulatory & Scientific Affairs
2645 Matheson Blvd. E.
Mississauga, Ontario
Canada L4W 5S4

APR - 1 2011

Re: K102948
Trade/Device Name: TorFlex™ Transseptal Guiding Sheath
Regulatory Number: 21 CFR 870.1340
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DYB; DQY; DRE
Dated: March 24, 2011
Received: March 25, 2011

Dear Mr. Khakhar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

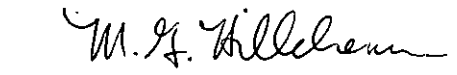
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part.803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K102498

Device Name: TorFlex™ Transseptal Guiding Sheath

Indications For Use:

The TorFlex™ Transseptal Guiding Sheath is used for the percutaneous introduction of various types of cardiovascular catheters to all heart chambers, including the left atrium via transseptal perforation / puncture.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102948